

REMARKS

The following remarks are in response to the Examiner's Final Office Action mailed on August 10, 2005. Claims 2 and 9 have been canceled; and claims 16–20 withdrawn. Claims 1, 6, 10, and 15 are amended. New claims 21–26 are added. Claims 1, 3–8, and 10–26 are pending.

I. Rejection under 35 U.S.C. §103(a)

Claims 1–13 and 15 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Davis (U.S. Patent No. 5,610,077) in view of Glaunsinger et al. (2000) (Oncogene 19:5270–5280) and Bleul (U.S. Patent No. 5,753,233). In addition, claim 14 is rejected under 35 U.S.C. §103(a) as being unpatentable over Davis in view of Bleul and Glaunsinger et al. and further in view of Kehmeier et al. (2002) (Virology 299:72–87).

Independent claims 1, 6 and 10 as amended specify a method or system for detecting the presence of an oncogenic HPV in a sample by using a PDZ domain polypeptide of less than 1000 amino acid in length and comprising the amino acid sequence of MAGI-1 PDZ domain 2. Support of the amended language appears in the specification, for example, at page 8, line 25; for new dependent claims 21–23 at page 8, lines 20–28; for new independent claim 24 at page 8, lines 19–20, and page 25, lines 7–8, for new dependent claim 26, at page 85, Table 3A, and at page 86, Table 3B.

In contrast, none of the cited references, each alone or in combination, teaches or suggests the claimed invention. Specifically, Davis does not teach or suggest detection of an oncogenic strain of HPV, let alone teaches or suggests detection of an oncogenic strain of HPV by using a polypeptide comprising a PDZ domain 2. Bleul merely discloses serum-reactive epitopes on HPV that could be used to detect HPV 18 E6 protein in blood serum (Abstract; and claims 1–10), thus fails to teach the claimed invention.

Glaunsinger et al. also fails to teach or suggest the claimed invention of detection of an oncogenic HPV by using a PDZ domain polypeptide of less than 1000 amino acid in length and comprising the amino acid sequence of MAGI-1 PDZ domain 2. Glaunsinger et al. merely

describes experiments to show that in the cell, the full-length MAGI-1 is a target for HPV E6 for degradation and suggests that “the tumorigenic potentials of the viral oncoproteins depend on, in part, on an ability to inhibit the function of MAGI-1 in cells.” See Abstract; and page 5278, column 1, last paragraph. Nowhere does this reference teach or suggest detection of oncogenic HPV by using a PDZ polypeptide of less than 1000 amino acid in length and comprising the amino acid sequence of MAGI-1 PDZ domain 2. In fact, according to Glaunsinger et al., the full length MAGI-1 has a molecular weight of 152 KD (page 5271, column 1, last paragraph), thus is significantly longer than 1000 amino acid in length. As acknowledged by the Examiner, Glaunsinger et al. does not teach a fragment of MAGI-1, let alone teaches or suggests using a PDZ domain polypeptide shorter than 1000 amino acid in length for the detection of an oncogenic HPV.

Further, Kehmeier et al. fails to meet the deficiency of Davis, Bleul and Glaunsinger in order to render the claimed invention *prima facie* obvious. Specifically, Kehmeier merely discloses inhibition of cellular proteasome-dependent degradation (*see Abstract*) and thus does not teach or suggest detection of an oncogenic strain of HPV by using a polypeptide comprising a PDZ domain 2.

In view of the distinct structural and functional differences between the claimed invention and the methods disclosed in the cited references, a *prima facie* case of obviousness has not been established under 35 U.S.C. §103(a). Withdrawal of the rejection is therefore respectfully requested.

II. Obviousness-Type Double Patenting

Claims 1-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting in view of claims co-pending patent application 10/847,818.

Independent claims 1, 6 and 10 as amended are patentably distinct from the claims of 10/847,818 because the instant claims recite “a PDZ domain polypeptide of less than 1000 amino acid in length and comprising the amino acid sequence of MAGI-1 PDZ domain 2.” These elements are not present in and are not reasonably suggested by the claims of 10/847,818. Thus, the claims of these two applications are patentably distinct from each other. Withdrawal of the obviousness-type double patenting rejection is therefore respectfully requested.

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CONCLUSION

In view of Applicants election, Applicants respectfully request the Examiner to expedite the prosecution of this patent application to issuance. Should the Examiner have any question, the Examiner is encouraged to telephone the undersigned.

The Commissioner is authorized to charge any additional fees that may be required, including petition fees and extension of time fees, or credit any overpayment to Deposit Account No. 23-2415 (Attorney Docket No. 31470-701.501).

Respectfully submitted,

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